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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1218

Docket No. CPSC-2010-0028

Safety Standard for Bassinets and Cradles

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing a safety standard for bassinets and cradles in response to the direction under Section 104(b) of the CPSIA.

DATES: The rule will become effective on April 23, 2014, with the exception of § 1218.2(b)(3)(i) through (iv), (b)(5), and (b)(7), which will become effective on April 23, 2015. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of April 23, 2014.

FOR FURTHER INFORMATION CONTACT: William Dewgard, Directorate for Compliance, Consumer Product Safety Commission, telephone: 301-504-7599; e-mail: WDewgard@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be substantially the same as applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as “a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.” Bassinets and cradles are specifically identified in section 104(f)(2)(L) of the CPSIA as a durable infant or toddler product.

On April 28 2010, the Commission issued a notice of proposed rulemaking (NPR) for bassinets and cradles. 75 FR 22303. The NPR proposed to incorporate by reference the voluntary standard, ASTM F2194-07a^{e1}, *Standard Consumer Safety Specification for Bassinets and Cradles*, with certain changes to provisions in the voluntary standard to strengthen the ASTM standard.

The Commission published a supplemental notice of proposed rulemaking (SNPR) on October 18, 2012. 77 FR 64055. The SNPR proposed to incorporate the voluntary standard, ASTM F2194-12, with: (1) modifications to sections pertaining to scope and terminology and the

stability test procedure, and (2) the addition of new provisions for a segmented mattress flatness test and a removable bed stability requirement.

In this document, the Commission is issuing a safety standard for bassinets and cradles. Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this standard, largely through the ASTM process. The rule incorporates the voluntary standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles* (ASTM F2194-13), by reference, with the following modifications and additions: a clarification to the scope of the bassinet/cradle standard; a change to the pass/fail criterion for the mattress flatness test; an exemption from the mattress flatness requirement for bassinets that are less than 15 inches across; the addition of a removable bed stability requirement; and a change to the stability test procedure requiring the use of a newborn CAMI dummy rather than an infant CAMI dummy.

II. The Product

ASTM F2194-13 defines “bassinet/cradle” as a “small bed designed primarily to provide sleeping accommodations for infants, supported by free standing legs, a stationary frame/stand, a wheeled base, a rocking base, or which can swing relative to a stationary base.” While in a rest position, a bassinet/cradle is intended to have a sleep surface less than or equal to 10° from horizontal. The bassinet/cradle is not intended to be used beyond the age of approximately five months or when a child is able to push up on his hands and knees. Bassinet and cradle attachments for non-full-size cribs or play yards are considered part of the bassinet/cradle category, as are bedside sleepers that can be converted to four-sided bassinets not attached to a bed.

Cribs, Moses baskets, and products used in conjunction with an inclined infant swing or stroller, and products that are intended to provide only an inclined sleep surface of greater than 10 degrees horizontal, are not included under the category of “bassinets/cribbs.” (A Moses basket is a portable cradle for a newborn or infant, often made of straw or wicker, that can be used with a variety of rocking and stationary stands. As with other bassinets and cradles, Moses baskets are not intended for use after a child can push up on its hands and knees.) However, Moses baskets and carriage accessories that can be converted to a bassinet or cradle by attachment to a separate base/stand would be considered bassinets/cribbs when used with the base/stand. Similarly, products that could be used at an incline of 10 degrees or less from horizontal, as well as more than 10 degrees from horizontal, would be considered bassinets/cribbs when in the flatter configuration(s).

III. Incident Data

The preamble to the SNPR summarized incident data involving bassinets and cradles reported to the Commission as of January 18, 2012. 77 FR 64055 (October 18, 2012). CPSC’s Directorate for Epidemiology, Division of Hazard Analysis has updated this information to include bassinet- and cradle-related incident data reported to the Commission from January 18, 2012 through March 31, 2013. A search of the CPSC epidemiological databases showed that there were 71 new incidents related to bassinets and cradles reported during this time frame. Thirty-eight of the 71 were fatal, and 33 were nonfatal. Sixteen of the nonfatal incidents involved injuries. Almost all of the new incidents reportedly occurred between 2010 and 2012. Reporting is ongoing, however, so the incident totals are subject to change.

A. Fatalities

The majority of the deaths (32 out of 38) were asphyxiations due to the presence of soft or extra bedding in the bassinet, prone placement of the infant, and/or the infant getting wedged between the side of the bassinet and additional bedding. All but four of the 38 decedents were five months or less in age, the ASTM-recommended age range for bassinet use; three of the decedents were six months old and another was an eight-month-old.

Two of the 38 deaths were associated with design aspects of the product. One of these was a suffocation death in a corner of the bassinet whose rocking feature contributed to its non-level resting position; the other fatality occurred when the bassinet was knocked over by an older sibling.

There were three fatalities with insufficient information and one fatality with confounding information preventing CPSC from determining the hazard scenario.

B. Nonfatal Incidents

A total of 33 bassinet-related nonfatal incidents were reported from January 18, 2012 through March 31, 2013. Of these, 16 reports indicated an injury to an infant using the bassinet or cradle at the time of the incident. The majority of these injuries (11 out of 16, or 69 percent) were due to falls out of the bassinets. All 11 fall injuries were reported through NEISS, with little or no circumstantial information on how the fall occurred. However, the reports do indicate that 55 percent of the injured infants who fell out of bassinets were older than the ASTM-recommended maximum age limit of five months. All of the falls resulted in head injuries. Among the remaining five nonfatal injuries, mostly head injuries, no hospitalizations were reported. All but six of the injured were five months or less in age.

The remaining 17 incident reports indicated that no injury had occurred or provided no information about any injury. However, many of the descriptions indicated the potential for a serious injury or even death.

C. Hazard Pattern Identification

The hazard patterns identified in the 71 new incident reports were similar to the hazard patterns that were identified in the incidents considered for the SNPR and are grouped in the following categories (in descending order of frequency of incidents):

1. *Non-product-related issues:* Thirty-four of the 71 reports (48 percent) concerned incidents that involved no product defect or failure. This category consisted of 32 fatalities that were associated with the use of soft/extra bedding, prone positioning, and/or the infant getting wedged between the side of the bassinet and additional bedding. In addition, there were two nonfatal injury incidents that did not involve any product-related issues.
2. *Product-related issues:* The hazard scenarios in 25 of the 71 reported incidents (35 percent) were attributed to a failure/defect or a potential design flaw in the product. This category includes one fatality and 13 injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:
 - Reports of infants falling or climbing out of bassinets/cribbedles accounted for a total of 13 incidents, all of which were received from emergency departments around the United States. Eleven of the incidents reported a nonfatal injury; the remaining two infants were reported to be uninjured.

- Lack of structural integrity, which includes issues such as instability, loose hardware, and product collapse, among others, was reported in nine incidents—one with a fatality and two with nonfatal injuries.
 - Problems with accessories (such as the stand or sheets), which were sold with the bassinets, were reported in two incidents. However, no injuries were reported.
 - One other product-related problem, involving the battery compartment of an older product, was reported in one non-injury incident.
3. *Recalled product-related issues:* There were six reports (eight percent) that were associated with three different recalled product-related issues. (Two of the recalls were published since the incident data for the SNPR briefing package was presented; at the time, these issues were classified under the “structural integrity” and “rocking” categories.) Although there were no injuries, there was a fatality included among the six incident reports. In the fatal incident, it is reported that the tilting of the bassinet caused the decedent to roll and press up against the side and suffocate.
4. *Miscellaneous other issues:* The remaining six incident reports (eight percent) were related to other unspecified issues. The reports described the incidents with insufficient specificity or provided confounding information, preventing CPSC staff from identifying the hazard scenario. There were four fatalities, one nonfatal injury, and one non-injury incident reported in this category.

IV. Overview of ASTM F2194

ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*, establishes safety performance requirements, test methods, and labeling requirements to minimize the identified hazard patterns associated with the use of bassinets/cradles. ASTM first

published a consumer product safety standard for bassinets and cradles in 2002. The standard was revised several times over the next 11 years. The current version of the standard is ASTM F2194-13. The more significant requirements of ASTM F2194 include:

- Scope—describes the types of products intended to be covered under the standard.
- Spacing of rigid side components—is intended to prevent child entrapment between both uniformly and non-uniformly spaced components, such as slats.
- Openings for mesh/fabric—is intended to prevent the entrapment of children’s fingers and toes, as well as button ensnarement.
- Static load test—is intended to ensure structural integrity even when a child three times the recommended (or 95th percentile) weight uses the product.
- Stability requirements—is intended to ensure that the product does not tip over when pulled on by a two-year-old male.
- Sleeping pad thickness and dimensions—is intended to minimize gaps and the possibility of suffocation due to excessive padding.
- Tests of locking and latching mechanisms—is intended to prevent unintentional folding while in use.
- Suffocation warning label—is intended to help prevent soft bedding incidents.
- Fabric-sided openings test—is intended to prevent entrapments.
- Rock/swing angle requirement—is intended to address suffocation hazards that can occur when latch/lock problems and excessive rocking or swinging angles press children into the side of the bassinet/cradle.
- Occupant restraints—is intended to prevent incidents where unused restraints have entrapped and strangled children.

- Side height requirement—is intended to prevent falls.
- Segmented mattress flatness—is intended to address suffocation hazards associated with “V” shapes that can be created by the segmented mattress folds.

The voluntary standard also includes: (1) torque and tension tests to prevent components from being removed; (2) requirements for several bassinet/cradle features to prevent entrapment and cuts (minimum and maximum opening size, small parts, hazardous sharp edges or points, and edges that can scissor, shear, or pinch); (3) requirements for the permanency and adhesion of labels; (4) requirements for instructional literature; and (5) corner post extension requirements intended to prevent pacifier cords, ribbons, necklaces, or clothing that a child may be wearing from catching on a projection.

V. The SNPR and ASTM F2194-13

The SNPR proposed to incorporate by reference ASTM F2194-12, with four modifications/additions to the voluntary standard:

- 1) **Scope and Terminology:** The SNPR proposed excluding inclined products from the scope of the standard, by revising the scope and including a detailed note with examples of what products were and were not included in the scope of the standard. The SNPR also proposed two existing definitions be revised for clarity.
- 2) **Segmented Mattress Flatness Test:** The SNPR proposed a new test requirement and associated test procedure to address suffocation incidents in segmented mattresses. As discussed in the preamble to the SNPR, the mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission’s

pass/fail criteria proposed in the SNPR, a bassinet attachment with a segmented mattress would fail if any tested seam creates an angle greater than 10 degrees.

3) Removable Bed Stability Requirement: The SNPR proposed a new test requirement and associated test procedure to address fatal and nonfatal incidents associated with bassinets that have removable bassinet beds. In the proposed requirement, a removable bassinet bed that was not properly attached or assembled to its base would be required to meet one of the following requirements:

- a. The base/stand shall not support the bassinet (*i.e.*, the bassinet bed falls from the stand so that it is in contact with the floor); or
 - b. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
 - c. The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
 - d. The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product to indicate whether the bassinet is properly attached to the base; or
 - e. The bassinet shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.
- 4) Stability Test Procedure: The SNPR proposed a revised test procedure for stability. The revision specifies the use of a newborn CAMI dummy, rather than the six month CAMI dummy that is referenced in the ASTM standard.

The SNPR's provisions concerning the scope and terminology and the proposed segmented mattress flatness test requirement were balloted by ASTM in 2012, and the provisions

are now included in the latest revision of the voluntary standard, ASTM F2194. Although the mattress flatness test procedure in ASTM F2194-13 is identical to what is proposed in the SNPR, the pass/fail criterion is different. As stated previously, under the Commission's pass/fail criteria, as proposed in the SNPR, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees.

The removable bed stability requirement proposed in the SNPR is not in the current ASTM standard, but a similar version is expected to be balloted by ASTM for inclusion in the next revision. Similarly, the change in the stability test procedure proposed in the SNPR is not in ASTM F2194-13, but it is expected to be balloted by ASTM for inclusion in its next revision.

VI. Response to Comments

There were 27 comments received on the SNPR, including: one from Health Canada; one from a group of consumer's groups (Kids In Danger, Consumers Union, American Academy of Pediatrics, Consumer Federation of America, Public Citizen, and U.S. PIRG); one from the Juvenile Products Manufacturers Association (JPMA); and two from bassinet manufacturers. The remaining 22 comments were from consumers, law students, or unaffiliated sources. The comments raised several issues, which resulted in two changes to the final rule. Several commenters made general statements supporting the overall purpose of the proposed rule. All of the comments can be viewed at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC-2010-0028. Following is a summary of and responses to the comments.

Scope

Comment: Two commenters provided almost identical comments and suggestions for changes to the scope. The commenters asserted that the scope was unclear about what products are included in the scope and under what conditions. For instance, one comment stated that it was not clear from the SNPR how products with an inclined seat back surface (reclined seat back), such as infant seats, infant bouncer seats, and infant rockers that do not provide an “inclined sleep surface” would be treated under the standard.

Response: The scope that was proposed in the SNPR has subsequently been adopted by ASTM and is the scope in the current version of the ASTM standard, ASTM F2194-13. The comments received reflect continued ambiguity regarding some aspects of the scope. Therefore, the Commission is providing additional clarity in the final rule.

Inclined products fall under a variety of different ASTM standards, depending on the product’s function. For instance, ASTM standards include a handheld carrier standard, an infant bouncer standard, and a new rocker standard that is currently under development. None of those products is intended for sleep. An inclined product intended for sleeping would fall under the inclined sleep product standard currently under development by ASTM. The Commission’s intent is that the scope of the bassinet standard exclude all inclined products when the incline is more than 10 degrees from horizontal.

However, the Commission intends that any product that has both a flat (10 degrees or less) sleep surface and an inclined surface greater than 10 degrees from horizontal shall fall under the scope of the bassinet standard when configured in the flat mode, and will fall under the scope of the appropriate inclined product standard(s) while in the inclined mode. In this manner, all uses of the product are addressed by safety standards. This type of product is considered a

multimode product, or a combination product, *i.e.*, the product can convert from one use mode to another.

During the recent ASTM F15 juvenile products subcommittee meetings held in April 2013, scope clarity was raised in various product subcommittees where multimode products are commonly considered. Most of those product subcommittees proposed to modify the scope section of the appropriate standard to clarify that these combination products shall fall under the scope of all relevant standards when in the corresponding use mode.

This intent to include multimode products under multiple standards is well established in ASTM standards, including the bassinet standard. One example of a multimode product is a carriage basket that is removable from a stroller base. The scope section of ASTM F2194-13 clearly states that products used in conjunction with a stroller are not covered by the standard. Yet, the current scope section also states: “Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1.” Clearly, the intent of the ASTM standard is to see that this multimode product falls within the scope of the stroller standard when attached to the stroller frame and falls within the scope of the bassinet standard when attached to a separate frame/stand.

Thus, to remove any ambiguity regarding multimode products, the Commission’s standard modifies the note that accompanies the scope provision of ASTM F2194-13 to clarify that a multimode product with a bassinet-use mode must meet the bassinet standard when in the bassinet-use mode.

Comment: One commenter suggested that the scope of the standard needs more specific age restrictions.

Response: The scope of a standard is intended to define broadly an entire product category.

Within that category, manufacturers have the freedom to tailor their product to a specific market niche, which might be more specialized than other products in the same category. Providing too many specific restrictions within the scope of a standard makes the standard weaker by excluding many products that ought to be included. In general, ASTM standards are defined by their respective industries, using terms that produce a standard that is as useful as possible to that industry. The Commission agrees with the bassinet industry on the existing age recommendations in the ASTM standard.

Removable Bassinet Bed Requirements

Comment: One group of commenters suggested that the Commission eliminate the two “passive” pass conditions (20 degrees and passing stability) of the removable bassinet bed stability requirement in favor of the other pass criteria, which the group of commenters said they believe makes the user actively aware that the bassinet is not attached properly.

Response: The SNPR proposed several options to meet the removable bassinet bed requirements. This approach is less restrictive than prescribing one pass criterion, and the approach allows for more innovation in product designs. By permitting five different options to meet this requirement, manufacturers have a variety of design choices available.

Comment: Some commenters said they believe that allowing the bassinet to “fail” (by falling to the ground or to a 20 or more degree angle) encourages manufacturers to make products that are less stable to ensure that their bassinets pass this requirement. Another commenter stated that it was foreseeable that some caregivers may attempt to attach the bassinet bed to its stand while the child is in the product and that this might expose children to unnecessary hazards.

Response: Two of the five options to pass the removable bed requirement are closely related to one another. These two options are: (1) the sleep surface shall be at least 20 degrees off from a horizontal plane; and (2) the bassinet bed falls from the stand and contacts the floor. These two requirements were added after consultations with stakeholders (ASTM task group members). Several stakeholders stated that if a bassinet stand was designed to support the bassinet bed only if it were locked properly, then the bassinet stand should be able to pass the requirement. For instance, in the case of a stand that looks like a saw horse, or “A” frame that has a lock/latch connection at the top of the “A” on the frame and on the underside of the bassinet bed, the caregiver would have to line up both halves of the lock/latch to attach the bed to the stand. It would be unreasonable to believe that caregivers would place the bassinet bed on an “A” frame stand without engaging the lock/latch because the design of the stand would cause the bassinet bed to fall to the ground if the lock was not engaged.

Rather than specifying a design requirement, the task group converted the requirement to a performance requirement, by simulating what would happen if the unreasonable act occurred. In other words, this option requires the bassinet bed to fall to the ground if the lock is not properly engaged.

Once that requirement was vetted by the task group, another stakeholder raised the possibility that the bassinet bed, in the act of falling, might get caught on the stand before hitting the ground. The stakeholder asserted that simply because the bassinet bed did not hit the ground should not constitute a failure. Thus, the 20-degree tilt option was added to address the possibility that the bassinet bed, in the process of falling, might get caught on the stand and to complement the fall-to-the-ground option.

A bassinet that relies on either of these two options to pass the requirement would be considered to provide immediate positive feedback. Caregivers who attempt to place the bassinet bed on this type of stand without locking it in place will realize instantly that they did not engage the lock because the bassinet bed will not assume a stable position that allows the caregivers to release their grasp. The immediate feedback of instability will minimize the possible hazards, making falling unlikely. The Commission believes that the steep angle needed to pass is unlikely to allow consumers to let children fall. The instability of such a unit is immediately obvious to the user, precluding a delayed response. Consumers are likely to check the stability of the product before removing their hands from it. Even in the case of a caregiver who attempts to place an occupied bassinet bed on a stand using this option, the caregiver will be present and potentially will be able to prevent or arrest the fall of the bassinet bed. The Commission considers the possibility of a fall hazard in this scenario to be highly unlikely; and on the rare chance that a fall occurs, the fall in these circumstances would be considered less significant than an unattended fall to the floor.

Comment: One commenter stated that the option—"The lock/latch shall automatically engage under the weight of the bed (without any other force/action)"—should be a requirement for all bassinets.

Response: The Commission is providing manufacturers with options to meet the removable bassinet bed requirements. This approach is less restrictive than prescribing one requirement and allows for more innovation in product designs.

Comment: One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter expressed the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue working on the issue.

Response: The Commission is aware of two deaths associated with this hazard scenario. (One of these deaths occurred in Canada; thus, it was not included in incident data counts reported in the SNPR briefing package.) Therefore, the Commission does not believe that this requirement is premature. The Commission believes that stakeholders have had plenty of time to test, review, discuss, and refine the proposed requirements before and after the SNPR was published. In fact, the language recommended for the final rule is essentially the same as what ASTM expects to ballot soon as a new requirement to address the same hazard.

Comment: A commenter stated that color-only visual indicators should not be allowed as an option to pass the removable bassinet bed requirement because people who are color-blind would not be able to distinguish between locked and unlocked.

Response: The requirement for visual indicators allows manufacturers to design a visual indicator that can be recognized by a person with a color vision deficiency. In addition, there are many other options to pass the requirement, and individuals who are color-blind can choose to purchase a product that does not use color indicators.

Comment: Some commenters expressed a belief that allowing removable bassinet beds to pass the stability test by tilting to a 20-degree angle was hazardous because consumers might think that a 20-degree angle is still usable, perhaps as an inclined sleeper.

Response: The Commission believes that an angle of 20° or more is acceptable to demonstrate that the bassinet is not useable. A steeper angle would also be acceptable, but the Commission is not convinced this is needed. Twenty degrees is twice the maximum allowable tilt for bassinets, which are intended to have a flat sleeping surface. In deciding on the 20° angle, the ASTM task group noted an incident (101101HCC3107) where a consumer clearly saw that something was

wrong with his bassinet when he saw it tilted and deemed it to be unusable. From the photos, the tilt was estimated to be approximately 17.°

Mattress Flatness

Comment: Some commenters suggested that the mattress flatness requirements should be limited to 8° from the horizontal rather than 10.°

Response: Although the Commission would be amenable to using this more conservative margin of safety, *i.e.*, a tolerance of 16° of motion rather than 20,° the industry has maintained that a larger tolerance is necessary, due to the inherent variability of manufacturing products with fabric and foam. The industry claims that tighter tolerances on a segmented mattress made with the materials that are commonly used in these products would make it impossible to manufacture such mattresses. The Commission believes that the 10° limit is adequate to protect the expected user population.

Comment: A commenter suggested that the threshold limit for flatness should be 14° to preserve test-retest reliability.

Response: ASTM F2194-13 now includes the mattress flatness test requirement and procedure, as written in the SNPR, with the exception of the angle requirement. ASTM's requirement allows the use of an average for measurements over 10° and under 14,° while the SNPR proposed a maximum allowable measurement of 10.° Based on testing performed by an ASTM task group that was established to assess the reliability and repeatability of the mattress flatness test, the reliability of the test is adequate when the test is performed on products designed to pass the test. The commenter did not provide any new or different information to the Commission to support the suggestion for using the averaging method; thus, the Commission continues to support the 10° flatness criterion as proposed in the SNPR.

Comment: Some commenters questioned the use of a cylinder as a surrogate for a human occupant, and another commenter suggested that an automated human model would be more appropriate.

Response: An automated human model is not readily available. It is customary in the juvenile product industry to use easily manufactured shapes made from common materials. This testing strategy enhances the repeatability of the test. An ASTM task group conducted a repeatability and reproducibility study to compare various surrogates for use in the mattress flatness test. The cylinder was the best choice, based on the study results.

Comment: Some commenters suggested using the dummy in the test for mattress flatness so that infant position would be a factor.

Response: The test cylinder is a repeatable method that identifies hazardous products to the satisfaction of industry and the Commission. Unfortunately, the CAMI dummy is too stiff to be useful for simulating suffocation positions and would not be suitable to serve that purpose.

Comment: Some commenters wanted more explanation of how the cylinder sufficiently simulates an infant rolling into a mattress crease, as demonstrated in the mattress flatness test.

Response: The Commission has examined bassinets that pass the test and bassinets that fail.

When visual comparisons and measurements of angles are made to compare the movements of the mattresses during a test using an anthropomorphic dummy versus tests using a cylinder, few discernible differences are evident. The shape of the test weight does not seem to be as important as the mass of the test weight in identifying hazardous products.

Comment: Two commenters offered opinions about the mattress flatness testing and designs of bassinet accessories that use support rods underneath the mattress. One of the two comments suggested that the mattress flatness test be performed with and without the bars in place.

Moreover, the commenter suggested that if the bars are required to be in place to pass the flatness test, then they should be attached permanently. Similarly, the other comment suggested that the frame supporting the floor (mattress) should come preassembled to eliminate the possibility that the consumer can misassemble the product.

Response: The Commission agrees with these comments. In January 2013, ASTM balloted a revised mattress flatness test, requiring that any segmented mattress that has consumer-assembled mattress support rods, be tested with and without the mattress support rods. This requirement resulted from the Commission's play yard misassembly NPR that was published in August 2012. The ballot item passed and is now part of ASTM F2194-13. The final rule incorporates by reference ASTM F2194-13; thus, the test will include the suggestion from the commenters.

Comment: A commenter stated that that the mattress flatness test could not be performed on bassinets that were less than 15 inches wide because of the width of the cylinder and the block used in that test method. Furthermore, the commenter noted that such a small, narrow occupant-retention space would not present the same hazards involved in incidents with wider play yard bassinet accessories.

Response: The Commission agrees that bassinets with occupant-retention spaces that are narrower than the test apparatus are unlikely to be used with an infant placed orthogonally between walls that are so narrow. In the case where an infant is placed in a narrow bassinet correctly and then moves or shifts 90,^o the narrowness of the bassinet would likely not permit the infant to lie in a fully prone position, face down in an orthogonal seam. Thus, an exemption from the flatness test for mattress pad seams that run orthogonally between the sides of a bassinet

with a width of 15 inches or less seems reasonable. Therefore, the Commission is modifying the standard to exempt from the mattress flatness test bassinets that are narrower than 15 inches.

Effective Date

Comment: We received several comments on the effective date proposed in the SNPR. One commenter, representing several advocacy groups, supported the six-month effective date proposed in the SNPR. A second commenter agreed, expressing concerns that if the date were extended and a death occurred, “consumers might view the death as the result of the CPSC putting the interests of for-profit entities . . . ahead of the safety of infants who use their products.”

In contrast, several other commenters, including one manufacturer, recommended longer effective dates to reduce the impact of the rule, particularly for small businesses that have “fewer resources and connections within the industry” and that “may have to significantly alter their means of production.” Suggested effective dates ranged from 9 to 15.5 months, with commenters recommending that the CPSC focus on relief for firms that would be disproportionately impacted by the rule. Commenters suggested longer effective dates for firms newly covered by the expanded scope, and firms whose products would be subject to the removable bassinet bed requirement.

A manufacturer commenting on the effective date stated that a longer effective date is needed for firms that will need to redesign their products to meet the removable bassinet bed requirement. This firm stated that an effective date of at least 15.5 months is needed to reflect accurately the challenges of redesigning the product.

Response: The Commission recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process to meet the new removable

bassinet bed provision. Based on a comment from one manufacturer who stated it would need a minimum of 15.5 months to redesign its product, the Commission considers 18 months to be a reasonable time period to accommodate other manufacturers that might also need to redesign their products. Therefore, the Commission is implementing a six-month effective date for the final rule, with the specific exception of extending the effective date for the removable bassinet bed test requirement to 18 months.

Stability Testing – CAMI Dummy

Comment: Some commenters suggested using an infant and a newborn dummy in the stability test methods, while others said they believe the incident data do not support the need to change from an infant dummy to a newborn dummy because this change neglects the evidence that larger infants also use bassinets and cradles.

Response: The use of both dummies is unnecessary because the worst case scenario for stability is the smaller size dummy. The larger size dummy makes the product more stable. Therefore, if a product passes with a newborn, the product will also pass with an infant. Performing the test with two different dummies would be redundant and would only add to the cost of testing.

The Commission is requiring use of the newborn CAMI to make the test more stringent. Even if a majority of the incidents were not directly attributable to product stability, the instability of the product, in many incidents, was to blame, including two fatal incidents (one of which was reported from Canada).

Incident Data Analysis

Comment: Some commenters asserted that a causal relationship could not be established for fatalities that the Commission attributed to design defects. They also stated that the information used by the Commission to analyze fall incidents was circumstantial. Other commenters

suggested that additional information should be collected to determine the extent to which product design was at fault, to evaluate the cause of falls, and to “improve and expand on the regulations and guidelines set forth in the proposed rule.”

Response: The Commission gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. Although the Commission agrees with the commenters that additional information-gathering on all nonfatal injuries could be useful, given resource limitations, the Commission cannot follow up on every injury report with an in-depth investigation. Many of the nonfatal injuries were based on emergency department-treated cases from NEISS hospitals, and confidentiality requirements often prevent any additional contact with patients. In addition, even with cases that are followed, completion of the investigation is not guaranteed because of a lack of consumer cooperation or the inability to establish contact with the consumer.

Short of a controlled experimental setting, causal links are difficult to establish from observational data based on un-witnessed incidents. However, the combined judgment of subject matter experts at CPSC, corroborated by investigating state/county/local officials, supports the conclusions.

Comment: One set of commenters expressed the belief that the data presented in the SNPR is skewed and purposely misleading. There were specifics outlined in the comment, which are addressed in the response.

Response: The Commission disagrees strongly with the commenters’ assertion regarding the way the data are presented. For fatalities, the commenters contend that almost all of the incidents were due to caregiver negligence, even the ones that the Commission considered to be product related.

The commenters first argued that the Commission needed to gather more information on the fatalities deemed by the Commission to be product related. CPSC staff gathered as much information as possible on every cited product-related fatality through an in-depth, on-site field investigation. Because these incidents were not witnessed, the judgments of subject matter experts at CPSC and state/county/local investigating officials were combined to arrive at the conclusions about the manner of the deaths.

Second, the commenters asserted that of the three deaths that were due to infants sliding out of the fabric-sided opening, two were of the infants were older than the recommended-user age. Hence, the commenters further asserted, these two deaths cannot be counted as product-related because they were the result of caregiver negligence. The Commission disagrees with this assertion because the third decedent, who died in the same manner, was well within the recommended age limit. Therefore, the age of the other two decedents, barely a month above the recommended age limit, was deemed not to be a factor in the entrapments.

Third, the commenters stated that the non-product-related deaths appear to be due to caregiver negligence and do not justify CPSC's increasing the economic burden on manufacturers through added regulations. This argument has no basis because CPSC's regulation does not make any changes to the current voluntary standard based on these non-product-related fatalities.

For the nonfatal injuries, the commenters said they believe there is no justification for placing a burden on manufacturers by including one injury, due to a moldy mattress, in the report. CPSC staff includes all in-scope incidents in its hazard sketch, even if the Commission is not proposing any provisions to address the issue. Therefore, the manner in which staff reports the incident data does not impose any burden on manufacturers.

In addition, the commenters argued that six percent of the injuries from bassinets that were damaged during delivery were instances of blatant negligence on the part of the owners. First, to clarify, the Commission reported that six percent of the incidents, not injuries, involved bassinets damaged during delivery. Second, there were no injuries associated with these incidents, and the Commission did not propose any provisions to address the issue.

Comment: Some commenters said that the Commission needs to provide justification for its statement that the descriptions in the noninjury incident reports indicated the potential for serious injury. The commenters stated that without any further explanation, the statement seems “arbitrary.”

Response: CPSC staff has reviewed a number of incidents in which the caregiver was reported to be nearby and was able to rescue the infant from danger. Similar scenarios, with the infant unattended, have led to less favorable outcomes. Thus, the potential for serious consequences is not conjecture, and the statement is justified.

Size and Weight Limits

Comment: Some commenters suggested that the weight of an infant occupant should be considered in the standard’s scope to safeguard infants who exceed the recommended weight and size.

Response: The maximum weight of an occupant is already considered in the static load requirements in ASTM F2194-13, which the rule incorporates by reference. The industry requires a bassinet to be loaded to three times the manufacturer’s recommended weight. The side heights are also intended to account for the largest infants who might still use the bassinet.

Bassinet Misuse

Comment: One commenter expressed concern that the possibility of consumer misuse of bassinets would negate any effects of the new requirements.

Response: The Commission believes that strengthening the standard is the best way to improve product safety and that if significant product misuse becomes evident in injury reports, more developments are possible.

Comment: Another commenter suggested that educational campaigns about the proper and improper uses of bassinets would be sufficient.

Response: The Commission believes that educational campaigns play an important role in injury prevention but are best preceded by mechanical and physical safety requirements designed to make accidents as unlikely as possible to occur.

Restraints

Comment: One commenter expressed the belief that the lack of incidents with harnesses could be due to other factors, as much as to the lack of harnesses in bassinets.

Response: Deaths and injuries in other infant products have been attributed to restraints/harness that were not used or were used improperly. Therefore the Commission is not making any changes regarding the current prohibition of restraints in bassinets.

Warnings

Comment: Some commenters recommended the use of pictures or visual aids to clarify the warning messages.

Response: The Commission acknowledges that well-designed graphics can be useful in certain circumstances. However, the design of effective graphics can be difficult. Some seemingly obvious graphics are poorly understood and can give rise to interpretations that are opposite the intended meaning (so called “critical confusions”); therefore, a warning pictogram should be

developed with empirical study and well tested on the target audience. Although the Commission may take action in the future if it believes graphic symbols are needed to reduce the risk of injury associated with these products, the rule permits, but does not mandate, such supporting graphics.

With respect to the idea of creating a pictogram to communicate the dangers of soft bedding, the Commission agrees that a well-developed and tested pictogram could increase comprehension and acknowledges that such elements could be developed with some empirical study; the Commission, however, does not have the resources for such a project at this time and could not validate a warning graphic without research. However, there are a number of products for which such a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of this, an ASTM cross-product ad hoc working group may be the best place to develop such a pictogram. This could foster cross-product harmonization of such a pictogram and would allow testing and validation of the pictogram. CPSC staff will gladly participate in any such group, and should the need arise, staff will consider future action once such a graphic is developed.

Comment: A commenter suggested adding statistics to the suffocation warning.

Response: Crafting a warning requires balancing the brevity of the message with its attention-grabbing features and informational content. Too much information makes a long label that is likely to be ignored by consumers. On the other hand, too little information leaves consumers unsure of the message. CPSC staff's opinion is that the addition of statistical information on the suffocation warning label will not increase the effectiveness of the warning.

Comment: A commenter suggested that the warnings contain the maximum recommended age of the bassinet occupant, *i.e.*, five months.

Response: The current warning contains a developmental milestone, rather than an age maximum. Developmental milestones have the advantage of allowing for individual variability in use patterns. Some children will gain strength and coordination faster than others and will need to be removed from the bassinet sooner. Since children's abilities are more important than their age when evaluating the applicability of the warning, the age is not included in the warning.

Comment: A commenter suggested that the warnings should be displayed in a prominent position.

Response: The ASTM standard, which the rule incorporates by reference, already contains a common definition for "conspicuous" warnings in Section 3.3.3, with corresponding requirements in Sections 8.3, 8.4, and 8.5.

Comment: A commenter suggested strengthening the warning labels by requiring mattress pads to have the following statement: "This padding has been tested to reduce the risk of suffocation to a minimal level," adding that "additional padding increases this risk substantially and has caused fatalities."

Response: Although the standard does contain a requirement for the mattress pad to remain level, the standard does not contain a test for reducing the risk of suffocation created by the softness of the padding, which seems to be the assumption made by the commenter. The standard already contains a warning in Section 8.4.2, instructing against the use of additional bedding materials. This required warning must be visible to the consumer when the product is in the manufacturer's recommended-use position. Thus, the warning will not be covered by sheets, which are allowed, and will be more effective than on the mattress pad where any messages will be covered.

Comment: Another commenter suggested that consumers need to be warned of the hazards associated with segmented mattresses.

Response: Warnings are the last stage at which attempts are made to remove a hazard from a product. Changing the product is more effective. The standard contains performance requirements designed to eliminate the hazards associated with segmented mattresses, so it is not necessary to include a warning.

Comment: Several commenters suggested that warnings should have larger fonts, duplication on opposing walls of the bassinet, duplication on the packaging and on the product, more detailed hazard descriptions, and more information in supporting educational materials and product advertisements.

Response: Although CPSC staff agrees that any warning could be strengthened with a size, color, or other graphical features, the product's final appearance also needs to be considered because exceptionally large or graphic warnings may cause consumers to remove or deface the warnings, thereby rendering them ineffective for later users. The current warning requirements match industry standards for many juvenile products.

The Necessity for a Standard

Comment: Several commenters stated that the proposed standard for bassinets and cradles should not be adopted because the number of injuries and fatalities due to design defects was very low.

Response: The Consumer Product Safety Improvement Act (CPSIA) requires the Commission to issue a mandatory standard for bassinets and cradles, regardless of the number of incidents involving those products. Given the the CPSIA directive, the options are either to adopt the existing voluntary standard, as is, or revise the standard to make improvements. Even if a majority of the incidents were not directly attributable to defects in the product design, many incidents were. Congress mandated that CPSC adopt a more stringent standard if the

Commission determined that a more stringent standard “would further reduce the risk of injury.”

The Commission feels strongly that the final rule would do so.

Mattress Thickness (Rigid Products and Falls)

Comment: Some commenters expressed concern that the standard allows for rigid-sided bassinets with thicker mattresses than soft-sided bassinets. These commenters said they feel that thicker mattresses may pose more of a risk of babies falling out when a baby rolls to one side and the product tilts.

Response: There are two requirements in the existing ASTM standard, which the rule incorporates by reference, which would prevent the scenario described by the commenters. The first is the side height requirement, which states that the side height of the bassinet be 7.5" above the uncompressed surface of the mattress. Thus, if a bassinet maker supplies a thick mattress with the rigid-sided bassinet, the side heights must account for the thicker mattress and still yield 7.5" of side height above the mattress surface. In addition, the standard has a rock/swing angle requirement that limits the maximum angle a rocking bassinet can have, as well as a maximum rest angle it can have. The rest angle is measured using a CAMI doll placed up against the side of the bassinet. Thus, the standard uses a worst-case placement scenario for the occupant during the testing.

Health Canada Standard

Comment: A representative of Health Canada corrected a statement in the SNPR and the corresponding staff briefing package, which states: “The Canadian standard (SOR 86-962:2010) includes requirements for cribs and non-full-size cribs. This standard does not distinguish between a bassinet and non-full-size cribs.” The commenter noted that this overview statement

was incorrect because on November 18, 2010, the amended Cribs, Cradles, and Bassinets Regulations (SOR/2010-261) came into effect, and now bassinets are included in the scope.

Response: The Commission thanks Health Canada staff for the correction and the subsequent information regarding how SOR 2010/261 distinguishes bassinets, cradles, and cribs. As the Commission now understands, Health Canada defines these three products according to the sleep surface area contained in the product.

Play Yard Misassembly Requirement in Docket CPSC-2011-0064

Comment: The commenter repeated comments submitted for Docket CPSC-2011-0064, regarding the play yard misassembly requirement that was proposed in August 2012.

Response: The Commission has addressed these comments in the final rule briefing package for Play Yard Misassembly Requirement, dated June 26, 2013.

International Standards

Comment: Commenters remarked that more information regarding the international standards that were mentioned in the SNPR would be helpful.

Response: The Commission provided the names and designations of the standards, plus a description of where they differed substantially from the ASTM standard. Due to copyright laws, the Commission was not able to provide full copies of the standards. All of the standards are available for purchase online by anyone who seeks more information.

ASTM Copyright and Accessibility

Comment: Some commenters stated that the ASTM standard for bassinets and cradles should not be the basis of a mandatory rule because, as a copyrighted standard, the ASTM standard is not easily accessible to the public and creates an undue financial burden on small manufacturers and the general public.

Response: Section 104(b) of the CPSIA requires the Commission to issue standards for durable infant or toddler products that are substantially the same as applicable voluntary standards or are more stringent if more stringent standards would further reduce the risk of injury. Incorporating a voluntary standard, such as incorporating the ASTM standard by reference, is a well-recognized procedure for agencies. The incorporation satisfies the requirement of publication in the *Federal Register*. See 5 U.S.C. 552(a)(1)(E) (“matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register”).

Falls from Bassinets/Side Height

Comment: Some commenters suggested that the side height requirements need to be higher because consumers seem to be using bassinets with children older than the recommended ages. One commenter expressed the belief that the standard should match the Canadian side height requirement.

Response: The ASTM subcommittee discussed the side heights of bassinets for years. There was no side height requirement until recently. Consumers use the products longer than manufacturers recommend. High side heights could cause consumers to use their bassinets even longer than they have been using them because the older, larger children who can push up on their hands and sit unassisted will look safer in a bassinet with tall sides. The unintended consequence of taller sides might be an increase in falls from bassinets because older children are stronger and more agile than newborns. After much discussion, the ASTM subcommittee agreed to a 7.5-inch side height, based on the precedent set by the Canadians, who measure from the bottom of the bassinet rather than the mattress top. This difference in measurement landmarks makes it appear that the ASTM standard permits shorter sides; but in reality, the effective side height of a

bassinet in Canada is the same as in the ASTM standard. This side height requirement did not necessitate drastic changes in the bassinet designs on the market; so it would be unlikely that instituting the requirement would have any effect on consumer behavior.

Comment: Several commenters suggested that side height requirements might not be effective against misuse. One commenter expressed the belief that the burden should be placed on caregivers and that the standard needs no modification to address falls. Another suggested that warning labels should be strengthened instead.

Response: The side height requirement (7.5-inch minimum) is already part of ASTM F2194-13, which this rule incorporates by reference. The rule does not add anything further because the Commission believes that the requirements should be effective against misuse. The Commission believes that, at a minimum, this requirement will help protect infants who have not exceeded the maximum age requirement for bassinet use. Additionally, the Commission supports the current warnings in the ASTM standard.

Existing Inventory

Comment: One commenter expressed concern that the Commission did not address the existing cradle and bassinet inventory that would need “to be discarded or recalled” when the regulation becomes effective.

Response: The bassinet and cradle standard is prospective. It will apply to products manufactured or imported on or after the effective date. Therefore, existing inventory would not be affected.

Cost Benefit Analysis

Comment: Several commenters expressed the belief that a cost-benefit analysis should be performed, and they stated that the proposed rule should not be adopted because costs are likely to exceed benefits.

Response: Section 104(b) of the Consumer Product Safety Improvement Act (CPSIA), part of the Danny Keysar Child Product Safety Notification Act, requires the CPSC to issue a standard at least as stringent as the voluntary standard, or more stringent if the Commission determines that a more stringent standard would further reduce the risk of injury associated with such products. Thus, the Commission must issue a mandatory standard for bassinets and cradles, regardless of the costs and benefits of the rule.

Third Party Testing Cost

Comment: Two commenters expressed concern about the “substantial additional costs” that will result from a new requirement for third party testing that will be added by the bassinet/cradle standard.

Response: The testing costs referred to by the commenters result from the third party testing and certification requirements imposed under sections 14(a)(2) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA. The costs associated with testing will be substantially the same, regardless of the form the final bassinet/cradle standard takes.

Definition of a Small Business

Comment: One commenter questioned defining “small manufacturers” as those with fewer than 500 employees. The commenter noted that business size can vary widely within such a broadly defined group. The commenter expressed concern that the economic impact could be disproportionately significant for the very smallest firms.

Response: The U.S. Small Business Administration (SBA) is the source of the definition of “small manufacturers” of bassinets and cradles. Regardless of the desirability of a finer gradation in defining small businesses, the SBA definition governs the small business determination in the context of a regulatory flexibility analysis.

Impact of Expanding the Scope

Comment: One commenter expressed concern about the “adverse monetary impact” that expanding the scope of the standard to include Moses baskets would have upon some suppliers. The commenter felt that the alternative of ceasing to supply stands for these newly covered products requires further inquiry before “suggesting that this is a viable alternative.” Other commenters questioned methods firms might use to mitigate their “upfront costs,” including amortizing, “increased product sales,” and passing “the additional costs on to consumers.”

Response: When used with a stand, Moses baskets meet the definition of a “bassinet” (or “cradle,” in the case of a rocking stand), and therefore, they must be tested as a bassinet. Given that most suppliers of Moses baskets do not include stands, supplying Moses baskets without stands is one viable option that firms are already practicing.

Similarly, the statement that “direct impact may be mitigated if costs are treated as new product expenses that can be amortized” recognizes one of the methods firms use routinely in the development of new products to reduce the immediate financial impact; rather than incurring all of the development costs up front, amortizing allows the firm to spread the impact over time. Finally, for most products, firms are usually able to pass on some, but not all, increases in production costs to consumer. The portion of costs that are passed on (i.e. not absorbed by the firm) partially offset or mitigate the impact of the rule.

Aiding Small Businesses

Comment: One commenter suggested that the Commission “create a framework with which to aid some of the smaller manufacturers and distributors with finding the resources, information and connections they need to comply with the new standards.”

Response: CPSC’s Small Business Ombudsman provides small businesses with guidance to assist them in complying with CPSC requirements. Assistance is available to firms in understanding and complying with CPSC regulations (<http://www.cpsc.gov/en/Business--Manufacturing/Small-Business-Resources/>).

Small Bedding Suppliers

Comment: One commenter asked that the Commission put “less weight” on small bedding suppliers in the regulatory flexibility analysis. The commenter expressed concern that:

“[N]oncompliant bedding could potentially negate the efficiency of . . .” safety measures such as strangulation warnings “. . . or require manufacturers to take additional steps to correct noncompliant bedding.”

Response: The standard does not include any bedding requirements. However, in investigating the bassinet/cradle market, staff could not determine the underlying source of bassinets for several suppliers of bassinets. The firms for whom the bassinet source could not be identified shared one major characteristic: they were primarily bedding suppliers who sold bassinets or cradles with the appropriate bedding covering the bassinet/cradle frame. Because these firms supply bassinets/cradles, they are affected by the rule and impacts must be fully considered under the Regulatory Flexibility Act.

Labeling Costs

Comment: One commenter objected to the costs that will be associated with changing the warning labels.

Response: The commenter misunderstood the information presented in the Paperwork Reduction Act section of the SNPR. The commenter interpreted the cost per burden hour associated with labeling (\$27.55) to be the increased cost per unit, which is an incorrect conclusion.

VII. Assessment of Voluntary Standard ASTM F2194-13 and Description of Final Rule

Consistent with section 104(b) of the CPSIA, this rule establishes new 16 CFR part 1218, “Safety Standard for Bassinets and Cradles.” The new part incorporates by reference the requirements for bassinets and cradles in ASTM F2194-13, with certain additions and changes to strengthen the ASTM standard, to further reduce the risk of injury. The following discussion describes the final rule, the changes, and the additions to the ASTM requirements. (The description of the amendment to 16 CFR part 1112 may be found in Section XIII of this preamble.)

A. Scope (§ 1218.1)

The final rule states that part 1218 establishes a consumer product safety standard for bassinets and cradles manufactured or imported on or after the date that is six months after the date of publication of a final rule in the FEDERAL REGISTER, except that the effective date for the removable bassinet bed requirements would be 18 months after the date of publication of a final rule in the FEDERAL REGISTER.

B. Incorporation by Reference (§ 1218.2)

Section 1218.2(a) explains that, except as provided in § 1218.2(b), each bassinet and cradle must comply with all applicable provisions of ASTM F2194-13, “Standard Consumer Safety Specification for Bassinets and Cradles,” which is incorporated by reference. Section 1218.2(a) also provides information on how to obtain a copy of the ASTM standard or to inspect a copy of the standard at the CPSC. The Commission received no comments on this provision in

the SNPR, but the Commission is changing the language in the incorporation in the final rule to refer to ASTM F2194-13, the current version of the ASTM standard.

C. Changes to Requirements of ASTM F2194-13

1. Clarification of Scope. (§ 1218.2(b)(1)(i)). The final rule modifies the scope of ASTM F2194-13 to clarify that multimode combination products must meet the bassinet/cradle standard in any configuration where the seat incline is 10 degrees or less from horizontal. This modification resulted from comments on the SNPR seeking clarification on what products are included in the scope, as more fully discussed in Section VI.

2. Change to Stability Test Procedure. (§ 1218.2(b)(2) and § 1218.2(b)(6)). In the SNPR, the Commission proposed that bassinet/cradle stability testing be conducted with a CAMI newborn dummy, rather than the CAMI infant dummy. Because ASTM has yet to adopt this modification (although it is expected to be balloted in the near future), the Commission is including it in the final rule.

It is appropriate that the smaller newborn CAMI dummy be used for stability testing, because bassinets and cradles are intended to be used by very young children. The heavier (17.5-pound) infant CAMI currently specified for stability testing in ASTM F2194-13 could make these products more stable when tested than they would actually be in a real-world situation.

3. Removable Bassinet Bed. (§ 1218.(b)(3), (5), and (7)). In the SNPR, the Commission proposed adding a requirement for removable bassinet beds (along with test procedures and new definitions). As stated in the preamble of the SNPR (77 FR 64061), there have been several incidents involving bassinet beds that were designed to be removed from their stand, four of which have In-Depth Investigations. During the incidents, the bed portion of the unit was not locked completely or attached properly to its stand. The bed portion of the unit appeared to be

stable, giving the caregivers a false sense of security. For various reasons, the bed portion fell or tilted off of its stand. There have also been nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand, or the latch failed to engage as intended. In May 2012, 46,000 bassinets that could appear to latch to the stand when they actually had not latched were recalled.

(<http://www.cpsc.gov/cpscpub/prerel/prhtml12/12173.html>).

The SNPR proposed multiple options for a bassinet with a removable bed attachment to pass the proposed requirement. These options include: 1) ensuring that the bed portion of the bassinet is inherently stable when the bassinet bed is placed on the stand unlatched; 2) use of a false lock/latch visual indicator mechanism; 3) use of a stand that collapses if the bassinet bed is not properly attached; and 4) the presence of an obvious unsafe angle (more than 20 degrees) or a bassinet bed falls to the floor when it is not properly attached to the stand.

Since the issuance of the SNPR, ASTM has made several clarifying changes to the removable bassinet bed requirement, definitions, and test procedures, and ASTM is expected to send these changes out for ballot in the near future. Most of the differences are editorial changes to provide clarity to the test requirement and the test procedure. The significant, noneditorial differences between the requirement proposed in the SNPR and what ASTM is expected to ballot are as follows:

- The next ASTM ballot is expected to exclude play yard bassinets, as defined in the standard, from the removable bassinet bed definition. Thus, play yard bassinets would not be subject to the removable bassinet bed stability requirement.

- The next ASTM ballot is expected to expand on one of the pass criteria for the removable bed stability requirement, to allow bassinet stands that cannot remain in their proper use position unless the bassinet bed is properly attached.

The Commission agrees with these revisions and is adding the revised removable bassinet bed requirement as part of the final bassinet/cradle rule.

4. Mattress Flatness. (§ 1218.2(b)(4)(i)). A segmented mattress flatness requirement and associated test procedures were proposed by the Commission as part of the SNPR. ASTM adopted the requirement with modified, less stringent pass/fail criteria. The final rule modifies the pass/fail criteria in ASTM F2194-13 to mirror the SNPR proposal.

As stated in Section V, the mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. As discussed in the preamble to the SNPR, the 14-degree angle was based on an extrapolation of angles formed by dimensions of *average* infant faces. 77 FR 64060-64061. The Commission is uncomfortable using the *average* infant facial dimension as the basis for this requirement. Therefore, instead of using the average infant anthropometrics as a basis for the pass/fail criteria, the Commission continues to support using the smallest users' anthropometrics to set the test requirement of 10 degrees maximum for each measurement taken.

5. Exemption from Mattress Flatness Requirement. (§ 1218.2(b)(4)(i)). The final rule exempts from the mattress flatness requirement bassinets that are less than 15 inches across. These products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment.

VIII. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission is setting an effective date for the standard six months after publication for products manufactured or imported on or after that date, with the exception of the removable bassinet bed test requirement and procedure.

The Commission recognizes that some manufacturers will be required to redesign, test new prototype products, and then retool their production process in order to meet the new removable bassinet bed provision. Based on a comment from a manufacturer who asked for a minimum of 15.5 months to redesign its product, the Commission considers 18 months to be a reasonable time period to take into account other manufacturers who might also need to redesign their product. Therefore, the Commission is setting an 18-month effective date for the removable bassinet bed test requirement.

IX. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. 5 U.S.C. 604. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis when they promulgate a final rule, unless the head of the agency certifies that the rule will not have a significant

economic impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

B. The Market for Bassinets/Cradles

Bassinets and cradles are typically produced and/or marketed by juvenile product manufacturers and distributors, or by furniture manufacturers and distributors, some of which

have separate divisions for juvenile products. CPSC staff believes that there are currently at least 62 suppliers of bassinets and/or cradles to the U.S. market; 26 are domestic manufacturers; 19 are domestic importers; three are domestic retailers; and two are domestic firms with unknown supply sources. Twelve foreign firms currently supply the U.S. market: 10 manufacturers, one firm with an unknown supply source, and one importer that imports from foreign companies and distributes from outside of the United States. Eight additional firms specialize in children's bedding, some of which is sold with bassinets or cradles; the supply sources for these eight firms could not be identified.

Bassinets and cradles from 11 of the 62 firms have been certified as compliant by the Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers. Firms supplying bassinets or cradles would be certified to the ASTM voluntary standard F2194-12a, while firms supplying play yards with bassinet/cradle attachments would also have to meet F406-12a. (JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. ASTM F2194-12a was published in September 2012, and therefore, the standard would have become effective in March 2013. The more recent standard, ASTM F2194-12b, was published in December 2012, and therefore, that standard was not yet effective when research for this rule was conducted.) Twenty-four additional firms claim compliance with the relevant ASTM standard for at least some of their bassinets and cradles. Whether the bassinets or cradles supplied by the eight bedding suppliers comply with ASTM F2194 is not known.

According to a 2005 survey conducted by the American Baby Group (2006 Baby Products Tracking Study), 64 percent of new mothers own bassinets; 18 percent own cradles; and 39 percent own play yards with bassinet attachments. Approximately 50 percent of

bassinets, 56 percent of cradles, and 18 percent of play yards were handed down or purchased secondhand. Thus, approximately 50 percent of bassinets, 44 percent of cradles, and 82 percent of play yards were acquired new. These statistics suggest annual sales of a total of approximately three million units sold per year, consisting of about 1.3 million bassinets (.5 x .64 x 4 million births per year), 317,000 cradles (.44 x .18 x 4 million), and 1.3 million play yards with bassinet attachments (.82 x .39 x 4 million). (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, “Births: Final Data for 2010,” *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.)

National injury estimates were not reported by the Directorate for Epidemiology in the supplemental NPR or in the current FR briefing package because the data failed to meet NEISS publication criteria,. However, emergency department injury estimates over the approximately five years covered by the supplemental NPR and the current FR briefing package, from 2008 through 2012, averaged less than 250 annually. Based on data from the 2006 Baby Products Tracking Study, approximately 4.8 million bassinets and cradles were owned by new mothers. Therefore, the injury rate may be on the order of about 0.5 emergency department-treated injuries per 10,000 bassinets/cradles available for use in the households of new mothers ((250 injuries ÷ 4.84 million products in households of new mothers) x 10,000).

C. Reason for Agency Action and Legal Basis for the Rule

The Danny Keysar Child Product Safety Notification Act requires the CPSC to promulgate a mandatory standard for bassinets/cradles that is substantially the same as, or more stringent than, the voluntary standard. The Commission is adopting ASTM F2194-13 with five

modifications or additions that reflect: (1) changes proposed in the SNPR that are not part of F2194-13; (2) responses to public comments; and/or (3) additional work undertaken by ASTM, but not yet adopted. The changes will address a variety of known hazard patterns, including suffocation and positional asphyxia.

D. Requirements of the Final Rule

As stated in Section VII, the Commission is incorporating the voluntary standard for bassinets/crib, ASTM F2194-13, by reference, with five changes.

The Commission is implementing two modifications to ASTM F2194-13 in response to SNPR comments; neither is expected to have a negative impact on firms. The first is a modification to the scope that would clarify that multimode or combination products must meet the bassinet/crib standard in any configuration where the seat incline is 10 degrees or less from horizontal. Because the clarifying modifications do not change the scope of the standard, the modifications have no additional impact. The second is an exemption from the mattress flatness requirement for bassinets that are less than 15 inches across. Because of the characteristics of the narrower bassinets, these products are not subject to the hazard that the requirement is intended to address. Additionally, these narrower bassinets are not wide enough to test using the required procedures and equipment.

The Commission is implementing three additional changes to ASTM F2194-13, each of which is considered in separate sections below.

1. Stability testing

As stated in Section V of this preamble, in the SNPR, the Commission proposed that bassinet/crib stability testing be conducted with a CAMI newborn dummy, rather than the CAMI infant dummy. Because ASTM has yet to adopt this modification (although the

modification is expected to be balloted in the near future), the Commission is including the modification in the final rule. Based on limited testing, many bassinets/cribs appear to be able to pass this modified test procedure without modification. However, a few products may potentially require modifications to meet the revised stability test procedure. Staff believes that the modified test procedure is likely to affect only a few manufacturers, and likely will not require product redesign. Affected firms would most likely increase the stability of their product by widening the structure, making the bassinet bed deeper, or making the base heavier. The cost of meeting the modified requirement could be more significant if a change to the hard tools used to manufacture the bassinet is necessary. During the production process, a hard tool, which is a mold of the desired bassinet component shape, is injected with plastic or another material using a molding machine.

2. Mattress Flatness

A segmented mattress flatness requirement and associated test procedures were proposed by the Commission as part of the SNPR. ASTM adopted the requirement with modified (and less stringent) pass/fail criteria. The Commission is modifying the pass/fail criteria in ASTM F2194-13 to mirror the SNPR proposal.

The mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allows measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees.

Based on staff's testing, the play yard bassinet attachments of many suppliers (both compliant and non-compliant) appear to pass the requirement without any modifications. Bassinet attachments that would require some modification would need to increase the mattress support in their bassinets. Additional mattress support could be accomplished, for example, by retrofitting play yard bassinets to use longer rods or a better-fitting mattress shell. The cost of such a retrofit is unknown and would likely vary from product to product; however, a retrofit generally is less expensive than a product redesign.

3. Removable Bassinet Bed

As stated in Section V of this preamble, in the SNPR, the Commission proposed adding a requirement for removable bassinet beds (along with test procedures and new definitions). Since then, an ASTM task group has made several clarifying changes to the requirement, definitions, and test procedures and is expected to recommend them for ballot. The Commission is adopting the revised removable bassinet bed requirement as part of the final bassinet/cradle rule.

There are several firms supplying bassinets with removable bassinet beds to the U.S. market. The majority will require no modifications to meet the requirement. However, at least three firms are expected to need changes to one or more of their bassinets. Firms could meet the removable bassinet requirement in a number of ways, including redesigning the product entirely. However, many firms are likely to opt for less expensive alternatives, such as more sensitive locks that activate with little pressure (*i.e.*, with just the weight of the bassinet), where possible.

The costs and time involved in a redesign could be significant; one manufacturer stated in SNPR comments that the manufacturer would require 15.5 months to redesign its product to meet the removable bassinet bed requirement. Therefore, the Commission is setting an 18-

month effective date for this requirement, while maintaining a six-month effective date for the remainder of the final rule.

E. Other Federal or State Rules

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule). Section 14(a)(2) of the CPSA requires every manufacturer of a children's product that is subject to a product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards: (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product; (ii) for the testing of representative samples to ensure continued compliance; (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules; and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bassinets and cradles will be subject to a mandatory children's product safety rule, these products also will be subject to the third party testing requirements of section 14(a)(2) of the CPSA and the 1107 rule when the bassinet/cradle mandatory standard and the notice of requirements become effective.

F. Impact on Small Businesses

At least 62 firms are currently known to be marketing bassinets and/or cradles in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bassinets/cradles is small if the business has 500 or fewer employees; importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, about 39

of the 62 total firms are small firms—21 domestic manufacturers, 16 domestic importers, and two firms with unknown supply sources. An additional eight small firms supplying bassinets/cribbs along with their bedding; these may or may not originate from one of the 62 firms already accounted for. Other unknown small bassinet/cribb suppliers also may operate in the U.S. market.

Small Manufacturers

The expected impact of the final standard on small manufacturers will differ based on whether their bassinets/cribbs are already compliant with F2194-12a. (Play yards with bassinet attachments must comply with the effective play yard standard (F406), which includes a requirement that the attachment meet the bassinet/cribb standard.) In general, firms whose bassinets and cribbs meet the requirements of F2194-12a are likely to continue to comply with the voluntary standard as new versions are published. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Firms supplying bassinets and cribbs that comply with ASTM F2194-12a are likely also to comply with F2194-13 before the final bassinet/cribb rule becomes effective.

The majority of the changes to the voluntary standard (ASTM F2194-13) are the same as at the SNPR level; only the expanded scope proposed in the SNPR has been completely incorporated into the voluntary standard. Therefore, the expected impact of the final rule remains substantially the same as the impact presented in the initial regulatory flexibility analysis for the SNPR.

For manufacturers whose products are likely to meet the requirements of ASTM F2194-13 (14 of 21 firms), the direct impact could be significant for one or more firms if they must

redesign their bassinets to meet the final rule. Although the products of all firms would be subject to the stability testing requirements, in most cases, modifications are unlikely to be required and the costs are not expected to be significant. The products of five firms could be affected by the mattress flatness requirement (*i.e.*, they produce play yards with bassinet attachments), and at least three (and possibly five) of the known firms may be affected by the removable bassinet bed requirement. For the most part, the bassinets/cradles and bassinet cradle attachments supplied by these firms will be able to meet the changes to ASTM F2194-13 without modification. In cases where modifications are necessary, firms would most likely opt to retrofit their products, rather than undertake an expensive redesign. However, some products may require redesign, particularly to meet the new removable bassinet bed requirement, and therefore, costs could be significant in some cases. The Commission is adopting an 18-month effective date for the removable bassinet bed portion of the final rule to reduce the impact on affected firms.

Meeting ASTM F2194-13's requirements could necessitate product redesign for at least some bassinets/cradles not believed to be compliant with F2194-12a (7 of 21 firms). These firms could require redesign regardless of the modifications. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric, but could be more significant if changes to the frame are required, including changes to side height. One manufacturer estimated that a complete play yard redesign, including engineering time, prototype development, tooling, and other incidental costs, would cost approximately \$500,000. The Commission believes that a bassinet redesign would tend to be comparable. Consequently, the final rule could potentially have a significant direct impact on small manufacturers whose products do not conform to F2194-12a. Any direct financial impact may be mitigated if a firm

chooses to treat costs as new product expenses that can be amortized over time rather than a large, one time expense.

Some firms whose bassinets/cribbs are neither certified as compliant, nor claim compliance with F2194-12a, in fact, may be compliant with the standard. The Commission has identified many such cases with other products. To the extent that some of these firms may supply compliant bassinets/cribbs and have developed a pattern of compliance with the voluntary standard, the direct impact of the final rule will be less significant than described above. If two small firms with unknown supply sources, none of whose products appear to comply with F2194-12a, are manufacturers, these firms also may need to redesign their products to meet the final rule.

In addition to the direct impact of the final rule described above, the rule will have some indirect impacts. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the bassinet/cribb final rule; lead and phthalates testing is already required. Impacts of third party testing are not due directly to the bassinet/cribb rule's requirements, but are due to the testing rule's requirements. Consequently, impacts from the testing rule are indirect impacts from the bassinet/cribb final rule, and such indirect impacts could be significant.

One manufacturer estimated that testing to the ASTM voluntary standard runs around \$1,000 per model sample, although the manufacturer noted that the costs could be lower for some models where the primary difference is fabric rather than structure.

On average, each small domestic play yard manufacturer supplies seven different models of bassinets/cribbs and play yards with bassinet/cribb accessories to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$7,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F2194-13 is unlikely to be significant if only one bassinet/cribb sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third party testing costs could have a significant impact on a few of the small manufacturers.

Small Importers

As with manufacturers of compliant bassinets/cribbs, the seven small importers of bassinets/cribbs currently in compliance with F2194-12a could experience significant direct impacts as a result of the final rule if product redesign is necessary. In the absence of regulation, these importing firms would likely continue to comply with the voluntary standard as it evolves, as well as the final mandatory standard. Any increase in production costs experienced by their suppliers may be passed on to the importers.

Importers of bassinets/cribbs would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the final rule, which may be the case with the nine importers of bassinets/cribbs not believed to be in compliance with F2194-12a. Some could respond to the rule by discontinuing the import of their noncomplying bassinets/cribbs, possibly discontinuing the product line altogether. The impact of such a decision could be mitigated by replacing the noncompliant bassinet/cribb with a compliant bassinets/cribb, or by deciding to import an alternative product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, will experience costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers that must perform the testing themselves if more than one sample per model were required.

Other Possible Suppliers

Eight known small firms specialize in the supply of bedding, including bedding for bassinets and cradles, and the eight firms sell bassinet and cradle bedding *with* a bassinet or cradle. Although these firms do not manufacture the bassinets or cradles themselves, whether they purchase the bassinets or cradles domestically or from overseas is not known. These firms may source the bassinets and cradles sold with bedding in full or in part from one of the 62 firms discussed above. If the eight firms do not source from one of the 62 firms, then the eight firms represent additional suppliers to the U.S. market.

The eight firms with unknown supply sources would be affected in a manner similar to importers; they would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the final rule. Unlike most importers, however, the firms would not have the option of replacing a noncompliant bassinet/cradle with another product. Although the firms could opt to sell the bedding without the associated bassinet/cradle, such an approach would represent a change from their historical method of sale and might adversely impact their business strategy.

As with manufacturers and importers, these eight firms will also be subject to third party testing and certification requirements, and will experience costs similar to those for manufacturers if their supplying firm(s) does not perform third party testing. The resulting costs

could have a significant impact on some of these small bassinet or cradle suppliers that must perform the testing themselves.

G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Doing so would reduce the potential impact on firms whose bassinets/cribbs comply with the voluntary standard. However, because of the severity of the incidents associated with removable bassinet beds, instability, and mattress tilt, the Commission is not pursuing this alternative.

The Commission is imposing a six-month effective date for the final rule with an 18-month effective date, supported by SNPR comments submitted by one manufacturer, for the removable bassinet bed requirement. Setting a later effective date for either part will allow suppliers additional time to modify and/or develop compliant bassinets/cribbs and spread the associated costs over a longer period of time.

X. Environmental Considerations

The Commission's regulations address whether the Commission is required to prepare an environmental assessment or an environmental impact statement. These regulations recognize that certain CPSC actions normally have "little or no potential for affecting the human environment." One such action is establishing rules or safety standards for products. 16 CFR 1021.5(c)(1). This rule falls within the categorical exclusion.

XI. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3521). The preamble to the proposed rule (77 FR at 64055 through 64076) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Briefly, sections 8 and 9 of ASTM F2194-13 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0157 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated suppliers subject to the information collection burden is now estimated to be 62 firms, rather than the 55 firms initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1218	62	5	310	1	310

There are 62 known entities supplying bassinets to the U.S. market. All 62 firms are assumed to use labels already on both their products and their packaging, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about one hour per model. Each entity supplies an average of five different models of bassinets; therefore, the estimated burden associated with labels is 1 hour per model x 55 entities x 5 models per entity = 310 hours. We estimate that the hourly compensation for the

time required to create and update labels is \$27.55 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirement is \$8,540.50 (\$27.55 per hour x 310 hours = \$8,540.50).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB, and OMB has assigned control number 3041-0157 to the information collection.

XII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

XIII. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-

enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The safety standard for bassinets and cradles is a children's product safety rule that requires the Commission to issue an NOR.

The Commission recently published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as Part 1112). This rule became effective June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the bassinet and cradle standard, require an amendment to part 1112. Accordingly, this rule amends part 1112 to include the bassinet and cradle standard in the list with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for bassinets and cradles are required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1218, "Safety Standard for Bassinets and Cradles,"

included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

In connection with the part 1112 rulemaking, CPSC staff conducted an analysis of the potential impacts on small entities of the rule establishing accreditation requirements, 78 FR 15836, 15855-58 (March 12, 2013), as required by the Regulatory Flexibility Act and prepared a Final Regulatory Flexibility Analysis (FRFA). Briefly, the FRFA concluded that the requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would not likely pursue accreditation for this purpose. Similarly, amending the part 1112 rule to include the NOR for the bassinet and cradle standard would not have a significant adverse impact on small laboratories. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards and the only costs to them would be the cost of adding the bassinet and cradle standard to their scope of accreditation. As a consequence, the Commission certifies that the notice requirements for the bassinet and cradle standard will not have a significant impact on a substantial number of small entities.

To ease the transition to new third party testing requirements for bassinets and cradles subject to the standard and to avoid a “bottlenecking” of products at laboratories at or near the effective date of required third party testing for bassinets and cradles, the Commission, will,

under certain circumstances, accept certifications based on testing that occurred before the effective date for third party testing.

The Commission will accept retrospective testing for 16 CFR part 1218, safety standard for bassinets and cradles, if the following conditions are met:

- The children's product was tested by a third party conformity assessment body accredited to ISO/IEC 17025:2005(E) by a signatory to the ILAC–MRA at the time of the test. The scope of the third party conformity body accreditation must include testing in accordance with 16 CFR part 1218. For firewalled third party conformity assessment bodies, the firewalled third party conformity assessment body must be one that the Commission, by order, has accredited on or before the time that the children's product was tested, even if the order did not include the tests contained in the safety standard for bassinets and cradles at the time of initial Commission acceptance. For governmental third party conformity assessment bodies, accreditation of the body must be accepted by the Commission, even if the scope of accreditation did not include the tests contained in the safety standard for bassinets and cradles at the time of initial CPSC acceptance.
- The test results show compliance with 16 CFR part 1218.
- The bassinet or cradle was tested, with the exception of the removable bassinet bed attachment requirements, on or after the date of publication in the *Federal Register* of the final rule for 16 CFR part 1218 and before April 23, 2014. For bassinets or cradles that are subject to the removable bassinet bed attachment requirements, testing to the removable bassinet bed attachment requirements was conducted on or after the date of publication in the *Federal Register* of the final rule for 16 CFR part 1218 and before April 23, 2015.

- The laboratory’s accreditation remains in effect through April 23, 2014.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1218

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by adding paragraph (b)(33) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(33) 16 CFR part 1218, Safety Standard for Bassinets and Cradles.

3. Add a new part 1218 to read as follows:

PART 1218-SAFETY STANDARD FOR BASSINETS AND CRADLES

Sec.

1218.1 Scope.

1218.2 Requirements for bassinets and cradles.

Authority: Sec. 104, Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1218.1 Scope.

This part establishes a consumer product safety standard for bassinets and cradles manufactured or imported on or after April 23, 2014, except for the removable bassinet bed attachment requirements at § 1218.2(b)(3)(i) through (iv), (b)(5), and (b)(7), which are effective April 23, 2015.

§ 1218.2 Requirements for bassinets and cradles.

(a) Except as provided in paragraph (b) of this section, each bassinet and cradle must comply with all applicable provisions of ASTM F2194-13, Standard Consumer Safety Specification for Bassinets and Cradles, approved on April 1, 2013. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with ASTM F2194-13 standard with the following additions or exclusions:

(1) Instead of complying with Note 1 of section 1.3.1 of ASTM F2194-13, comply with the following:

(i) Note 1--Cradle swings with an incline less than or equal to 10° from horizontal while in the rest (non-rocking) position are covered under the scope of this standard. A sleep product that only has inclined sleeping surfaces (intended to be greater than 10° from horizontal while in the rest (non-rocking) position) does not fall under the scope of this standard. If a product can be converted to a bassinet/cradle use mode and meets the definition of a bassinet/cradle found in 3.1.1 while in that mode, the product shall be included in the scope of this standard, when it is in the bassinet/cradle use mode. For example, strollers that have a carriage/bassinet feature are covered by the stroller/carriage standard when in the stroller use mode. Carriage baskets/bassinets that are removable from the stroller base are covered under the scope of this standard when the carriage basket/bassinet meets the definition of a bassinet/cradle found in 3.1.1. In addition, bassinet/cradle attachments to cribs or play yards, as defined in 3.1.2 or 3.1.12, are included in the scope of the standard when in the bassinet/cradle use mode.

(ii) [Reserved]

(2) Add “CAMI Newborn Dummy (see Figure 1A). Drawing numbers 126-0000 through 126-0015 (sheets 1 through 3), 126-0017 through 126-0027, a parts list entitled “Parts List for CAMI Newborn Dummy,” and a construction manual entitled “Construction of the Newborn Infant Dummy” (July 1992). Copies of the materials may be inspected at NHTSA’s Docket Section, 400 Seventh Street S.W., Room 5109, Washington, DC, or at the Office of the Federal Register, 800 North Capital Street N.W., Suite 700, Washington, DC.” to “2.3 Other References” and use the following figure:

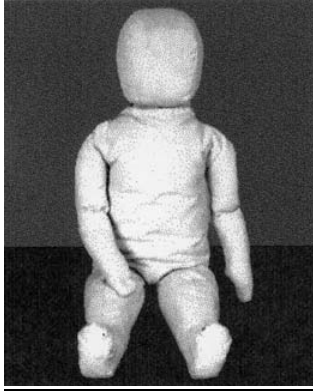


FIG. 1a CAMI Newborn Dummy

(3) In addition to complying with section 3.1.17 of ASTM F2194-13, comply with the following:

(i) 3.1.18 *bassinet bed, n* – the sleeping area of the bassinet/cradle, containing the sleep surface and side walls.

(ii) 3.1.19 *removable bassinet bed, n* – A bassinet bed that is designed to separate from the base/stand without the use of tools. Play yard bassinets, as defined in 3.1.13, are excluded from this definition.

(iii) 3.1.20 *false lock/latch visual indicator, n* – a warning system, using contrasting colors, lights, or other similar means designed to visually alert caregivers when a removable bassinet bed is not properly locked onto its base/stand.

(iv) 3.1.21 *intended use orientation, n* – The bassinet bed orientation (*i.e.*, the position where the head and foot ends of the bassinet bed are located), with respect to the base/stand, as recommended by the manufacturer for intended use.

(4) Instead of complying with section 6.7 of ASTM F2194-13, comply with the following:

(i) *6.7 Bassinets with Segmented Mattresses: Flatness Test*—If the bassinet or bassinet accessory has a folding or segmented mattress, or both, any angle when measured in 7.8 less than or equal to 10° is an immediate pass. Any angle when measured in 7.8 greater than 10° is an immediate failure. Segmented bassinet mattresses that have seams (located between segments or where the mattress folds) that are less than 15 inches in length are excluded from this requirement.

(ii) [Reserved]

(5) In addition to complying with section 6.9.2 of ASTM F2194-13, comply with the following:

(i) *6.10 Removable Bassinet Bed Attachment* - Any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand, shall comply with at least one of the following 6.10.1, 6.10.2, 6.10.3, 6.10.4 or 6.10.5 when tested in accordance with 7.12.

(ii) 6.10.1. The base/stand shall not support the bassinet bed (i.e., the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand).

(iii) 6.10.2. The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions (Figure 24).

(iv) 6.10.3. The sleep surface of the bassinet bed shall be at an angle of at least 20° from a horizontal plane when the bassinet bed is in an unlocked position.

(v) 6.10.4 The bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product.

(vi) 6.10.5. The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when tested in accordance with 7.12.5.3.

(6) Instead of complying with section 7.4.4 of ASTM F2194-13, comply with the following:

(i) 7.4.4 Place the CAMI Newborn Dummy, Mark II, on the sleeping pad in the center of the product face up with the arms and legs straightened.

(A) *Rationale.* The newborn CAMI dummy represents a 50th percentile newborn infant, which is a more appropriate user of a bassinet than the CAMI infant dummy, which represents a 50th percentile 6-month-old infant.

(B) [Reserved]

(ii) [Reserved]

(7) In addition to complying with section 7.11.4 of ASTM F2194-13, comply with the following:

(i) 7.12 *Removable Bassinet Bed Attachment Tests*

(ii) 7.12.1 Assemble the bassinet/cradle base/stand only, in accordance with manufacturer's instructions in one of the manufacturer's recommended use positions. If the base/stand does not remain in the use position when the bassinet bed is not locked onto it, the product meets the requirements of 6.10.1.

(iii) 7.12.2 Place the base/stand and the inclinometer on a flat level horizontal surface ($0 \pm 0.5^\circ$) to establish a test plane. Zero the inclinometer.

(iv) 7.12.3 Remove the mattress pad from the bassinet bed.

Note to paragraph (b)(7)(iv): For mattresses that are integral with the mattress support, do not remove the mattress and perform all angle measurements for 7.12 on a 6 by 6 by 3/8-in. nominal aluminum block placed on the center of the mattress.

(v) 7.12.4 Place the bassinet bed on the base/stand in the intended use orientation without engaging any latch or lock mechanism between the base/stand and the bassinet bed. If the bed automatically engages to the base/stand do not disengage the lock/latch. If the bassinet bed can rest on the base/stand in its intended use orientation in one or more lateral unlocked position (Figure 24), the unit shall be evaluated in the lateral position most likely to fail the requirements specified in 6.10.

(vi) Figure 24: Bassinet Bed Resting on Stand, Showing Possible Alternate Lateral Positions.

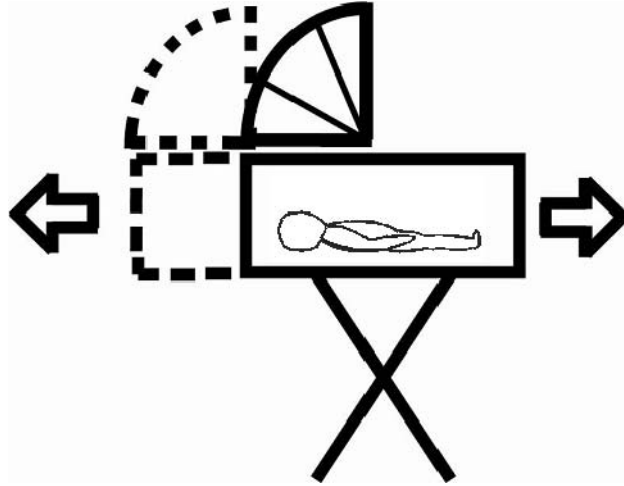


Figure 24: Bassinet Bed Resting on Stand,
Showing Possible Alternate Lateral Positions

(vii) 7.12.4.1 If the base/stand supports the bassinet bed in any unlocked position, place the inclinometer on the mattress support at the approximate center of the mattress support. Care should be taken to avoid seams, snap fasteners, or other items that may affect the measurement reading. Record the angle measurement.

(viii) 7.12.4.2 If the base/stand supports the bassinet bed and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, evaluate whether the bassinet has a false latch/lock visual indicator per 6.10.4.

(ix) 7.12.4.3 If the base/stand supports the bassinet bed, and the angle of the mattress support surface measured in 7.12.4.1 is less than 20 degrees from a horizontal plane, and the bassinet does not contain a false latch/lock visual indicator, test the unit in accordance with sections 7.4.2 through 7.4.7.

(x) 7.12.5 Repeat 7.12.2 through 7.12.4 for all of the manufacturer's base/stand recommended positions and use modes.

(xi) 7.12.6 Repeat 7.12.4 through 7.12.5 with the bassinet bed rotated 180 degrees from the manufacturers recommended use orientation, if the base/stand supports the bassinet bed in this orientation.

(A) *Rationale.* (1) This test requirement addresses fatal and nonfatal incidents involving bassinet beds that tipped over or fell off their base/stand when they were not properly locked/latched to their base/stand or the latch failed to engage as intended. Products that appear to be in an intended use position when the lock or latch is not properly engaged can create a false sense of security by appearing to be stable. Unsecured or misaligned lock/latch systems are a hidden hazard because they are not easily seen by consumers due to being located beneath the bassinet or covered by decorative skirts. In addition, consumers will avoid activating lock/latch

mechanisms for numerous reasons if a bassinet bed appears stable when placed on a stand/base. Because of these foreseeable use conditions, this requirement has been added to ensure that bassinets with a removable bassinet bed feature will be inherently stable or it is obvious that they are not properly secured.

(2) 6.10 allows bassinet bed designs that:

(i) Cannot be supported by the base/stand in an unlocked configuration,

(ii) Automatically lock and cannot be placed in an unlocked position on the base/stand,

(iii) Are clearly and obviously unstable when the lock/latch is misaligned or unused,

(iv) Provide a visual warning to consumers when the product is not properly locked onto the base/stand, or

(v) Have lock/latch mechanisms that are not necessary to provide needed stability.

(B) [Reserved]

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Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

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